K030258

510(K) SUBSTANTIAL EQUIVALENCE REVIEW SUMMARY

FEB 2 5 2003

Item	Section	Information
(1)	**Applicant Information**	A Company Name: Armkel, LLC B Mailing Address: 469 North Harrison St. Princeton, NJ 08543-5297 C Phone #: (609) 279-7748 D Fax#: (609) 497-7179 E Email address (optional): STEPHEN.KOLAKOWSKY@CHURCHDWIGHT.COM F Contact: Stephen C. Kolakowsky Director, Regulatory Affairs
(2)	**Proprietary & Established Names**	FIRST RESPONSE® Pregnancy Test
(3)	**Regulatory Information**	A Product Code: LCX (Panel 75) B Classification: II C CFR number: 21 CFR §862.1155 D Regulation name: Human chorionic gonadotropin (HCG) test system
(4)	**Intended Use(s)**	A Analyte: Human Chorionic Gonadotropin B Type of test: Qualitative C Specimen: Urine D Special instrument requirements: N/A E Special condition for use statement(s): OTC use only
(5)	**Substantial Equivalence Information**	A Predicate Device(s): FIRST RESPONSE® Pregnancy Test (FR) Clearblue Easy® Early Result Pregnancy Test (CB) B 510(k) number(s): K992232 (FR), K013372 (CB) C Comparison with predicate: The subject device and the predicate version of the FIRST RESPONSE® Pregnancy Test are identical. They differ only in the number of days prior to the expected menses the device can be used. The subject device is also very similar to the Clearblue Easy®. Both have the same intended use, both are immunochromatographic assays, both have similar test procedures, and both have similar performance (per analytical and consumer study data previously provided).
(6)	**Test Principle**	The device detects the presence of hCG in the urine of a pregnant woman by a series of immunochemical reactions via component reagents striped onto a chromatographic strip contained within plastic housing. For additional details, refer to K992232.

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(7) Specific Performance Characteristics

A Method comparison:
B Matrix comparison:
C Accuracy determination:
D Matrix comparison:
E Precision:
F Analytical Sensitivity:
G Analytical Specificity:
H Clinical or Diagnostic Sensitivity:
I Clinical or Diagnostic Specificity:
J Cut-off(s):
K Expected Values:

Please refer to K992232 for details on the specific performance characteristics.

(8) Other Relevant Information

The sponsor submitted this 510(k) to modify the number of days prior to the expected menses the device could be used. The FIRST RESPONSE® Pregnancy Test predicate version may be used as early as three (3) days before the expected menses and the Clearblue Easy® Early Result Pregnancy Test (predicate) may be used as early as four (4) days before the expected period. The subject device is proposed for use as early as four (4) days before the expected period.

As discussed on August 6, 2002 in a meeting between Church & Dwight Co., Inc. and FDA and in subsequent conversations, the sponsor has reinterpreted the same data provided in K992232 and revised the labeling to reflect the percentage of women in which the device detected the hormone 4 days before-, 3 days before-, 2 days before-, and 1 day before their expected period. Additionally, although there were no changes to the data set, the percentages for 3 days before-, 2 days before-, and 1 day before the expected period differ from those previously provided in the labeling. This is because the predicate test's claims were based on the percentage of cycles having quantitative hCG levels approximating the claimed sensitivity level or greater, even though hCG was detected days earlier in many of the conceptive cycles.

Veronica J. Calvin

Veronica J. Calvin, M.A.
Scientific Reviewer

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

ArmKel, LLC
c/o Mr. Stephen C. Kolakowsky
Director
Regulatory Affairs
Church & Dwight Co., Inc.
469 North Harrison Street
Princeton, NJ 08543-5297

FEB 2 5 2003

Re: k030258
Trade/Device Name: First Response® 1-Step Pregnancy Test
Regulation Number: 21 CFR 862.1155
Regulation Name: Human chorionic gonadotropin (HCG) test system
Regulatory Class: Class II
Product Code: LCX
Dated: January 23, 2003
Received: January 24, 2003

Dear Mr. Kolakowsky:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number:

Device Name: FIRST RESPONSE® 1-Step Pregnancy Test

Indications for Use: The FIRST RESPONSE® 1-Step Pregnancy Test is an *in vitro* diagnostic test device intended for the early detection of pregnancy by the lay user up to four (4) days prior to the expected menses

(Division Sign-Off)
Division of Clinical La
510(k) Number K030258

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-the-Counter Use X
(Per 21 CFR §801.109)